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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/341,505	07/12/1999	STEPHEN PHILIP JACKSON	MEWE-005	5221

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EXAMINER

LIU, SAMUEL W

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 05/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/341,505

Applicant(s)

JACKSON ET AL.

Examiner

Samuel W Liu

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 5-28 is/are pending in the application.
- 4a) Of the above claim(s) 5, 7-18, 20-21, 23 24 and 26-28 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 3 is/are allowed.
- 6) ☒ Claim(s) 6,19,22 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. PCT/GB98/00095.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The response filed 6 February 2003 (Paper No. 30) as to amendment of claims 1, 3, 6, 19, 22 and 25, and applicants' request for extension of time of one month filed 18 March 2003 (Paper No. 29) have been entered. Claims 1, 3, 6, 19, 22 and 25 are pending to which the followings are or remain applicable. Please note that grounds of objection and/or rejection not explicitly restated and/or set forth below are withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19, 22 and 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The compound obtained in any of the method of claims 1, 3 or 6 is not in hand or known. Therefore, one skilled in the art cannot make or use a compound obtained by theses methods to prepare the claimed pharmaceutical composition of the compound.

Factors to be considered in determining whether undue experimentation is required, are summarized in *Ex parte Forman*, 230 USPQ 546(BPAI 1986) and decision *in re Wands* 8 USPQ2d 1400, 1400 (Fed. Cir. 1998). They include the nature of the invention, the state of the art, the relative skill of those in the art, the amount of direction or guidance disclosed in the

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specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

(1) Presence or absence of working examples

There are no working examples in the specification teaching successful screening of a compound using the method of any one of claims 1, 3 or 6, and then, making a pharmaceutical preparation thereof.

(2) The amount of direction or guidance/ The predictability or unpredictability of the art

The specification teaches the methods to screen for the compound. However, the actual obtainment of the compound has not been demonstrated.

(3) The quantity of experimentation necessary:

One skilled in art would have to determine for the numerous compounds obtained by the screening methods, and such experimentation is undue.

(4) The nature of the invention/ The state of the prior art/ The relative skill of those in the art:

The current invention is based on complex screening methods which are novel. The skilled level of those in the art is thus high.

(5) Predictability and unpredictability of the art:

It is not predictable what compounds will be obtained by the screening methods because, on its face, a screening method is a method of finding compounds having a specific acting.

(6) Breadth of the claims:

Given the discussion above, the compounds obtained by the screening method could be nearly in any class of compound. Thus, the breadth is non-limiting.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view of the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

Thus, for all theses reasons, the specification does not enable the present claimed invention and would have resulted in the necessary of undue experimentation.

The response to the rejection under 35 USC 112, the first paragraph

The response filed 6 February 2003 discusses the issue of the two-hybrid assay, and infers that the two-hybrid technique is applicable to the multiple components of the current application (see page 8). The applicants' argument is not persuasive because the system only works for two components, but not for multiple (more than two) components forming a protein complex, e.g., XXRC4/DNA ligase IV/DNA-PK_{cs}/Ku. Additionally, because the disclosure is silent as to how XRCC4 protein interacts with DNA-PK_{cs}/ Ku, applicability of the yeast two-hybrid to the claimed screening method needs sufficient written description in order to support the enablement.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 6, 19, 22 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites "a screening method comprising ..."; a method of what? The recitation is unclear as to what is the subject matter of the claimed method. See also claims 19, 22 and 25.

Conclusion

Claims 1 and 3 are allowable, and claims 6, 19, 22 and 25 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483.

The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703 308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

Seu L

Samuel W. Liu, Ph.D.

April 23, 2003

Karen Cochrane Carlson
KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER